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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,928	10/23/2003	Jay A. Goldstein	JAG 100	1611

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EXAMINER	
STITZEL, DAVID PAUL	
ART UNIT	**PAPER NUMBER**
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/691,928	GOLDSTEIN ET AL.	
	Examiner	Art Unit	
	David P. Stitzel, Esq.	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

OFFICIAL ACTION

Acknowledgement of Receipt

Receipt of the Applicant's Declaration under 37 C.F.R. § 1.132, Substitute Amendment and Substitute Response, to the Official Action dated September 21, 2005, which were filed on December 27, 2005, is acknowledged.

Status of Claims

Claims 1-2, 4, 7 and 14 are amended, and claim 17 was added, by the aforementioned Substitute Amendment. As a result, claims 1-17 are currently pending and therefore examined herein on the merits for patentability.

Claim Rejections - 35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112, which forms the basis of the claim rejection as set forth under this particular section of the Official Action:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim as amended introduces new matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. More specifically, claim 1 recites "a low to low-medium potency steroidal anti-inflammatory ... in a concentration between 0.01 wt% and 5.0 wt%, and having a higher potency than 1 wt% hydrocortisone." In addition, Applicant directs the Examiner's attention to page 5, lines 13-15, of the instant specification (as providing

support for the recited claim amendment), which states in part that "hydrocortisone [in an amount of] 1% [by weight] ... would be minimally effective, if effective at all, in treating significant inflammation that accompanies fungal disease." However, inadequate support exists in said specification for amending said claim to recite "a low to low-medium potency steroidal anti-inflammatory ... in a concentration between 0.01 wt% and 5.0 wt%, and having a higher potency than 1 wt% hydrocortisone," thereby resulting in the addition of new matter. Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112, Second Paragraph

The rejection of claim 14 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention, is withdrawn as the phrase "preferred embodiment" was deleted from claim 14 by the aforementioned Substitute Amendment.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 102, which forms the basis of the anticipation rejections as set forth under this particular section of the Official Action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-10 and 13-17 are rejected under 35 U.S.C. § 102(a) as being anticipated by U.S. Patent 6,444,647 (hereinafter the Robinson '647 patent).

Similar to claims 1-10, 13 and 17 of the instant application, the Robinson '647 patent discloses an antifungal steroidal composition for treating fungal disease, wherein said composition (abstract) comprises an antifungal agent (column 30, lines 14-50) and a steroidal anti-inflammatory agent (column 26, lines 65-68; column 27, lines 1-33); wherein said antifungal agent is selected from the group consisting of clotrimazole, ketoconazole, miconazole and nystatin (column 30, lines 24-50), wherein said antifungal agent is present in an amount from 0.001% to 10% by weight of said composition (column 30, lines 14-23); wherein said steroidal anti-inflammatory agent is selected from the group consisting of desonide, fluocinolone acetonide, hydrocortisone butyrate, and hydrocortisone valerate (column 27, lines 9-33), wherein said steroidal anti-inflammatory agent is present in an amount from 0.1% to 10.0% by weight of said composition (column 27, lines 1-2); wherein said composition is formulated as a cream, ointment, gel, lotion, foam, powder, spray, shampoo or liquid solution for topical administration (column 20, lines 64-67; and column 37, lines 6-10). Similar to claims 14-16 of the instant application, the Robinson '647 patent discloses a method of treating scalp disorders comprising topically administering an antifungal steroidal composition to the skin of a subject during the subjects lifetime about once to about three times per day or more in an amount from about 0.1 mg/cm^2 to about 10 mg/cm^2 (column 36, lines 51-67; and column 37, lines 1-5).

2. Claims 1-5, 7-13 and 17 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 6,075,056 (hereinafter the Quigley '056 patent).

Similar to claims 1-5, 7-13 and 17 of the instant application, the Quigley '056 patent discloses an antifungal steroidal composition for the topical treatment of a tinea or candida fungal disease (abstract, and column 7, lines 25-30), wherein said composition comprises an antifungal agent and a

steroidal anti-inflammatory agent (abstract); wherein said antifungal agent is terbinafine (column 2, line 6), wherein said antifungal agent is present in an amount from 0.5% to 5% by weight of said composition (claim 2); wherein said steroidal anti-inflammatory agent is selected from the group consisting of aclometasone dipropionate, desonide, fluocinolone acetonide, hydrocortisone, hydrocortisone butyrate, and hydrocortisone valerate (column 5, lines 1-50), whereby said steroidal anti-inflammatory agent is present in an amount from 0.001% to 5.0% by weight of said composition (column 5, lines 56-58); wherein said composition further comprises a pharmaceutically acceptable excipient selected from the group consisting of well known solvents (i.e., propylene glycol), emollients (i.e., mineral oil), humectants (i.e., sorbitol), preservatives (i.e., benzyl alcohol), emulsifiers (i.e., glyceryl monosterate), buffers (i.e., hydrochloric acid, sodium hydroxide and monobasic sodium phosphate) and mixtures thereof (column 2, lines 53-67; column 3, lines 1-8); wherein said composition has a pH from about 3.5 to about 7.0 (column 3, lines 1-2) and is formulated as a cream, ointment, gel, lotion, foam, powder, aerosol, spray, shampoo or liquid solution for topical administration (column 7, lines 31-34).

3. Claims 1-9, 13-14, 16 and 17 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,686,089 (hereinafter the Mitra '089 patent).

Similar to claims 1-9, 13 and 17 of the instant application, the Mitra '089 patent discloses an antifungal steroidal composition for treating candida fungal disease (column 3, lines 12-13), wherein said composition comprises an antifungal agent (column 3, lines 35-40) and a steroidal anti-inflammatory agent (column 6, lines 65-67; and column 7, lines 1-29); wherein said antifungal agent is selected from the group consisting of clotrimazole, miconazole, terconazole and nystatin, wherein said

antifungal agent is present in an amount from about 0.01% to about 4% by weight of said composition (column 3, lines 35-40; and claim 1); wherein said steroidal anti-inflammatory agent is selected from the group consisting of desonide, fluocinolone acetonide, and hydrocortisone valerate, wherein said steroidal anti-inflammatory agent is present in an amount from about 0.1% to about 10.0% by weight of said composition (column 6, lines 65-67; and column 7, lines 1-29). Similar to claims 14 and 16 of the instant application, the Mitra '089 patent discloses a method of treating a candida fungal disease comprising topically administering an antifungal steroidal composition to an individual two times per day in an amount from about 1 mg to about 2 mg per cm^2 of skin (column 8, lines 66-68; and column 9, lines 1-16).

4. Claims 1-10 and 17 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,219,877 (hereinafter the Shah '877 patent).

Similar to claims 1-10 and 17 of the instant application, the Shah '877 patent discloses an antifungal steroidal composition for treating tinea and candida fungal disease (column 1, lines 6-14), wherein said composition comprises an antifungal agent and a steroidal anti-inflammatory agent (column 3, lines 10-14); wherein said antifungal agent is selected from the group consisting of clotrimazole, econazole and miconazole, wherein said antifungal agent is present in an amount from 0.1% to 5% by weight of said composition (column 3, lines 43-53); wherein said steroidal anti-inflammatory agent is selected from the group consisting of desonide, fluocinolone acetonide, hydrocortisone butyrate, and hydrocortisone valerate, wherein said steroidal anti-inflammatory agent that is present in an amount from 0.01% to 2.5% by weight of said composition (column 3, lines 54-65); wherein said composition is formulated as a gel for topical administration (column 3, lines 20-25).

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 103, which forms the basis of the obviousness rejections as set forth under this particular section of the Official Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 15 is rejected under 35 U.S.C. § 103(a) as being unpatentable over the teachings of the Mitra '089 patent.

Similar to claim 15 of the instant application, the Mitra '089 patent teaches a method of treating a candida fungal disease comprising topically administering an antifungal steroidal composition to an individual two times per day in an amount from about 1 mg to about 2 mg per cm^2 of skin (column 8, lines 66-68; and column 9, lines 1-16). Although the Mitra '089 patent does not specifically mention topically administering said antifungal steroidal composition to "a child of under 10 years old" "two times per day," the Mitra '089 patent explicitly states that although the amount of said antifungal steroidal composition and the frequency of treatment will vary widely depending upon the individual, it is suggested that said antifungal steroidal composition be applied about once per day to about four times per day, but preferably from about twice per day to about three times per day. One of ordinary skill in the art would immediately recognize modifying the amount and frequency of application of said antifungal steroidal composition based upon the age of the individual as well as the severity of the fungal infection. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because each and every element

of the claimed invention, as a whole, would have been reasonably disclosed or suggested by the teachings of the cited prior art references.

Examiner's Response to Applicant's Remarks

Although Applicants' Declaration under 37 C.F.R. § 1.132, and Remarks as set forth in pages 6-10 of the aforementioned Applicants' Substitute Response of December 27, 2005, have been fully considered, they are not persuasive.

More specifically, Applicants' Declaration under 37 C.F.R. § 1.132, which was filed on December 27, 2005, is insufficient to overcome the rejection of claims 1-16 under 35 U.S.C. § 102(a) and (b), as set forth in the Official Action dated September 21, 2005, because evidence of secondary considerations, such as unexpected results or commercial success, is irrelevant to, and therefore cannot overcome, 35 U.S.C. § 102 rejections. See, In re Wiggins, 179 USPQ 421, 425 (CCPA 1973); and MPEP § 2131.04.

Applicants' clinical observations and discoveries are nevertheless expected, as it is very well known in the art that ultra-high and high potency halogenated or fluorinated anti-inflammatory steroids cause serious side effects, whereas to the contrary, non-halogenated or non-fluorinated anti-inflammatory steroids (i.e., alclometasone dipropionate, desonide, fluocinolone acetonide, and hydrocortisones, such as hydrocortisone butyrate and hydrocortisone valerate) are among the least potent steroids and are preferred due to the minimization of, and low potential for, causing serious side effects. See e.g., U.S. Pre-Grant Patent Application 2003/0232086 ([0077], [0078]); U.S. Pre-Grant Patent Application 2002/0165170 ([0017], [0018]); U.S. Patent 6,395,721 (column 2, lines 1-31; column 4, Table 1, lines 10-57); U.S. Patent 5,998,395 (column 2, lines 19-68, Table I; column 3, lines 1-25, Table I continued); U.S. Patent 5,977,176 (column 3, lines 37-42); U.S. Patent 5,110,809

(column 4, lines 65-68; column 4, lines 1-2); and the National Psoriasis Foundation internet printout provided by Applicant explicitly stating that the risk of side effects are greater when utilizing topical steroids having stronger potencies.

With respect to the Applicant's arguments regarding the cited prior art references alleged failure to recognize that the side effects associated with halogenated or fluorinated high potency steroidal anti-inflammatories may be avoided by alternatively utilizing non-halogenated or non-fluorinated low potency steroidal anti-inflammatories, does not render the instantly claimed composition patentable over the prior art, as alclometasone dipropionate, desonide, fluocinolone acetonide, and hydrocortisones, such as hydrocortisone butyrate and hydrocortisone valerate, are inherently non-halogenated or non-fluorinated low to low-medium potency steroidal anti-inflammatories, regardless of whether the cited prior art references, which disclose an identical composition, explicitly characterize that said steroidal anti-inflammatories are non-halogenated or non-fluorinated and classified as being of low to low-medium potency. It is well established that "products of identical chemical composition can not have mutually exclusive properties," since a chemical composition and its properties are inseparable. See, *In re Spada*, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990); and MPEP § 2112. Therefore, where an Applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the instantly claimed composition, but the function, property or characteristic is not explicitly disclosed by the cited prior art reference, the Examiner may make a rejection under 35 U.S.C. § 102 and/or 35 U.S.C. § 103. See, MPEP § 2112. Where the claimed and prior art products are identical or substantially identical in structure or composition, a prima facie case of either anticipation or obviousness has been established. See, *In re Best*, 195 USPQ 430, 433 (CCPA 1977).

Remarks

The following is a list of prior art patents and publications made of record and considered pertinent to the applicant's disclosure, but are not however currently relied upon in construing the claim rejections as set forth herein:

- U.S. Pre-Grant Patent Application 2003/0232086 ([0077], [0078]);
- U.S. Pre-Grant Patent Application 2002/0165170 ([0017], [0018]);
- U.S. Patent 6,395,721 (column 2, lines 1-31; column 4, Table 1, lines 10-57);
- U.S. Patent 5,998,395 (column 2, lines 19-68, Table I; column 3, lines 1-25, Table I);
- U.S. Patent 5,977,176 (column 3, lines 37-42); and
- U.S. Patent 5,110,809 (column 4, lines 65-68; column 4, lines 1-2).

Conclusion

Although Applicants' remarks filed December 27, 2005, have been fully considered, they are not persuasive. In addition, Applicants' amendment adding new claim 17 necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a)

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to David P. Stitzel, Esq. whose telephone number is 571-272-8508. The Examiner can normally be reached on Monday-Friday, from 7:30AM-6:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Sreenivasan Padmanabhan can be reached at 571-272-0629. The central fax number for the USPTO is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published patent applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished patent applications is only available through Private PAIR. For more information about the PAIR system, please see http://pair-direct.uspto.gov. Should you have questions about acquiring access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David P. Stitzel, Esq.

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER